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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASTRA AKTIEBOLAG, *et al.*, Plaintiffs,	99-CIV-8926 (DLC) 99-CIV-9887 (DLC)
v.	
ANDRX PHARMACEUTICALS, INC., Defendant.	
In re OMEPRAZOLE PATENT LITIGATION	M-21-81 (DLC) MDL Docket No. 1291

ASTRA AKTIEBOLAG'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION *IN LIMINE* TO EXCLUDE EVIDENCE AND TESTIMONY RELATING TO NEW HYPOTHETICAL NEGOTIATION DATES

Andrx should be precluded from: i) offering a new hypothetical negotiation date, and ii) arguing that Astra's proposed hypothetical negotiation dates are incorrect. Defendant ("Andrx") represented to the Court and to Plaintiffs ("Astra") that the date of the hypothetical negotiation for determining a reasonable royalty and hence damages in this case, is September 2001 – consistent with Astra's contentions. Allowing Andrx to change its theory now would unfairly prejudice Astra. This unfairness is exacerbated by Andrx's inability to locate and produce documents that would likely have precluded Andrx from changing its position.

I. BACKGROUND

The most common method for calculating a reasonable royalty to determine damages, and the method used by the parties in this case, is called the hypothetical negotiation. The hypothetical negotiation seeks to arrive at the royalty that the parties would have agreed to had a successful negotiation occurred just before infringement began. *Lucent Technologies, Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009) (citing *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970).

Astra asserts that the date of the hypothetical negotiation is September 16, 2001 if Andrx's "validation" batches are infringing, or November 7, 2001 if they are not. (Ex. 1, Meyer Report, ¶ 34). September 16 is the date that manufacturing started[1] for the first commercial batch that Andrx contends was a validation batch. (Id.). November 7, 2001 is the date that manufacturing began for the first commercial batch, that Andrx produced full records for, that Andrx concedes was not a validation batch. (Id.). Andrx's experts have not provided any alternative hypothetical negotiation date. (*See, e.g.,* Ex. 2, Langenfeld Report, ¶ 34; *see also,* Ex. 3, Graves Report).

The date of the hypothetical negotiation impacts the amount of damages. Astra's damages take into account the advantage provided by the head-start obtained by Andrx manufacturing product earlier than it could have without a license. Astra's damages are not based only on the amount of infringing product Andrx manufactured.

After Astra served its damages expert report, Andrx indicated, through its responsive expert report and deposition questioning of Astra's damages expert, that it will argue for a

[1] There are three main steps to manufacturing the omeprazole product: First, the Active Pellet is produced. Second, the Active Pellets are coated to create Enteric-Coated Pellets. Third, the Enteric-Coated Pellets are placed into capsules. September 16 and November 7 are the dates that the Active Pellet manufacturing began, for the alleged validation and non-validation batches (based on the records Andrx was able to locate and produce), respectively.

hypothetical negotiation date later than November 7, 2001. Specifically, the Expert Report of Michael Graves alleges that the November 7, 2001 hypothetical negotiation date (for the case where the validation batches are not infringing) incorrectly references a validation batch, implying the date should be later. (Ex. 3, Graves Report, ¶ 129). Additionally, during the deposition of Dr. Meyer, Astra's damages expert, Andrx's counsel appeared to indicate that the hypothetical negotiation date should be the date the Enteric-Coated Pellets (second step) are manufactured, as opposed to the date the Active Pellets (first step) are manufactured as Astra contends, which if accepted would result in a later hypothetical negotiation date. (*See, e.g.,* Ex. 4, Meyer Deposition, 46:2-12).

II. ARGUMENT

A. Andrx Represented to the Court and Astra that September 2001 was the Hypothetical Negotiation Date

Andrx represented to the Court that September 2001 was the date infringement began, and accordingly, that this was the date of the hypothetical negotiation:

> THE COURT: Let's step back for my education. When we are doing this hypothetical negotiation to create an arm's length licensing fee, what is the date on which I am finding that negotiation or what is the period of time in which that negotiation occurred?
>
> MR. PERKOWSKI: It would be at the time of the infringement, which would be September of 2001.
>
> MR. TAYLOR: That's about the right time, your Honor, right before.
>
> MR. PERKOWSKI: We agree on something.

(Dkt. 78, Transcript of Conference with Court, Feb. 13, 2013, p. 18, ln. 25 – p. 19, ln. 9). Andrx should not be permitted to withdraw its representation to the Court. Andrx should not be

permitted to now argue that its infringement started later than September 2001 or that the hypothetical negotiation date was later than September 2001.

Andrx confirmed the September 2001 hypothetical negotiation date in its interrogatory responses. (Ex. 5, Andrx's Supplemental Response to Astra's First Set of Interrogatories, Mar. 13, 2012, p. 5). Specifically, when analyzing the *Georgia-Pacific* factors, "Andrx discusses each factor in turn and how each would apply to a hypothetical negotiation occurring in approximately September of 2001, immediately prior to the date of Andrx's manufacture of its ANDA product." (Id.). Andrx has not updated this interrogatory response, or provided Astra with any affirmative representation of what it believes the hypothetical negotiation date should be, other than September 2001.

B. Astra's November 7, 2001 Date is Supported by Andrx's Interrogatory Response

The batch Astra relied on to determine the November 7, 2001 hypothetical negotiation date (in the case where the validation batches were not infringing), ***was identified by Andrx*** as a non-validation batch. Specifically, Andrx's interrogatory responses state: "[t]he following are batches of finished, packaged omeprazole product manufactured before patent expiration that were *not research batches or part of the Validation Study*[,]" and goes on to identify Capsule batch 620C009. (Ex. 6, Andrx's Supplement Response to Astra's Interrogatory No. 4, June 19, 2013 ("Andrx's Response to Interrogatory No. 4"), p. 3). To determine the date when manufacture began for this batch, Astra reviewed the manufacturing records for the Capsule batch (third step), which identified the batches of Enteric-Coated Pellets that went into those capsules. Astra then reviewed the manufacturing records for the identified Enteric-Coated Pellets (second step), which identified the batches of Active Pellets that were used to make those Enteric-Coated Pellets. Finally, Astra reviewed the manufacturing records for the identified

Active Pellets (first step), to determine that the manufacture of those Active Pellets started on November 7, 2001.

Mr. Graves' expert report does not contend that Capsule batch 620C009 is a validation batch; rather, he contends that the Active Pellet batch used for those Capsules was a validation batch.[2] (Ex. 3, Graves Report, ¶ 129). After clearly representing that Capsule batch 620C009 was not a validation batch, Andrx should not now be allowed to argue that portions or intermediate parts of that batch were validation batches. Moreover, Andrx's interrogatory response specifically identifies those batches it contends are validation batches. (Ex. 6, Andrx's Response to Interrogatory No. 4, p. 9). Missing from that list is the Active Pellet batch Mr. Graves contends is a validation batch. (Id.).

Andrx served the interrogatory response on June 19, 2013. From that time, Astra has relied on Andrx's representations made in them. In addition, Astra's expert, Dr. Meyer, relied on that interrogatory response in conducting her damages analysis and drafting her expert report, served on July 1, 2013. The first time Andrx gave any indication that some portion of Capsule batch 620C009 was part of a validation batch was in the *responsive* expert report of Michael Graves, served on July 26, 2013.

Andrx should be precluded from arguing that batch 620C009, or any portion or part of manufacture thereof, is part of a validation batch, in view of Andrx's representation made in its interrogatory responses. In addition, such evidence and argument would be confusing to the jury, and be of little probative value.

C. Andrx Failed to Produce Manufacturing Records for the Earliest Batches

Andrx's Response to Interrogatory No. 4 identified non-validation batches with lower batch numbers than the batch relied on by Astra for the November 7, 2001 date, batch 620C009.

[2] Astra disagrees with, but does not address here, Andrx's position that this Active Pellet batch is a validation batch.

(Ex. 6, Andrx's Response to Interrogatory No. 4, p. 3). "[T]he last three digits [of Andrx's batch numbers] are sequential and indicate the number of lots manufactured during the year, starting with 001 for the first lot."[3] (Ex. 7, Batch Numbering Key, ANDRX0051694). For the five earliest (lowest numbered) 20-mg Capsule batches[4] identified by Andrx as "not research batches or part of the Validation Study," Andrx did not produce the underlying records that would allow Astra to determine when (Active Pellet) manufacturing for those Capsule batches started.

For example, no manufacturing records were produced for Capsule batch 620C002 – the batch Andrx identified as the first 20-mg non-validation batch. In addition, no manufacturing records were produced for Capsule batches 610C004 and 640C003 – the batches Andrx identified as the first 10-mg and 40-mg non-validation batches, respectively.

Astra informed Andrx that its batch record production was incomplete on June 18, 2013. (Ex. 8, Letter from E. Taylor to P. Perkowski, June 18, 2013). Astra then met and conferred with Andrx regarding the missing and incomplete manufacturing records. (Ex. 9, Letter from E. Taylor to P. Perkowski, June 24, 2013, p. 2). Andrx indicated that it believed it had made a reasonable effort to find and produce all manufacturing records, and, to the extent Astra did not have a record, Andrx was unable to locate it. (Id.).

These manufacturing records for the earliest infringing omeprazole batches (for which manufacture began *after* the start of the litigation) are exactly the type of records Andrx should have ensured remained preserved. Andrx should not be rewarded for its failure to locate or preserve these records. "When the calculation of damages is impeded by incomplete records of

[3] As indicated by Andrx's batch numbering key, the first three digits in the batch number represent the product (or intermediate product), and the letter represents the year of manufacture. (Ex. 7, Batch Numbering Key, ANDRX0051694). Specifically, for the first three digits representing the product, "061" means Active Pellets, "062" means Enteric-Coated Pellets, "610" means 10-mg Delayed-Release Capsule, and "620" means 20-mg Delayed-Release Capsule. (Id.). For the letter representing the date of manufacture, "B" means 2001, and "C" means 2002. (Id.). The last three digits start at "001," so a batch ending in "009" would be the ninth batch of omeprazole made that year. (Id.).

[4] Specifically, Capsule batches 620C002, 620C003, 620C004, 620C005, and 620C006.

the infringer, adverse inferences are appropriately drawn." *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1572 (Fed. Cir. 1996); *see also Beatrice Foods Co. v. New England Printing and Lithographing Co.*, 899 F.2d 1171, 1176 (Fed. Cir. 1990); *Kori Corp. v. Wilco Marsh Buggies and Draglines, Inc.*, 761 F.2d 649, 655 (Fed. Cir. 1985) ("Fundamental principles of justice require us to throw any risk of uncertainty upon the wrongdoer rather than upon the injured party.") (citing *Story Parchment Co. v. Paterson Parchment Co*., 282 U.S. 555, 563 (1931)). Accordingly, Andrx should be precluded from arguing a hypothetical negotiation date later than (or other than) the dates put forth by Astra. *Id.*

D. Andrx Failed to Argue a New Hypothetical Date

Andrx's experts have not provided any alternative hypothetical negotiation date. (*See, e.g.*, Ex. 2, Langenfeld Report, ¶ 34; *see also,* Ex. 3, Graves Report). For example, Dr. Langenfeld's expert report assumes the September 16 and November 7, 2001 dates put forth by Dr. Meyer (while noting that he has no opinion on whether these dates are correct). (Ex. 2, Langenfeld Report, ¶ 34).

To the extent Andrx believes a different date is appropriate, for example, the date the Capsule batch is released from quality control or some intermediate date in the production of the Capsules (of course, it would not be logical for Andrx to begin manufacturing the infringing omeprazole product, and then, mid-way through that manufacture, seek to negotiate a license with Astra), Andrx should have made that position clear in its contentions and expert reports. Allowing Andrx to put forth some novel theory as to the negotiation date for the first time at trial would be of little probative value to the jury, and be unfairly prejudicial to Astra.

III. CONCLUSION

For the reasons stated above, all evidence, argument and testimony regarding a new hypothetical negotiation date should be excluded from trial, and the hypothetical negotiation dates proposed by Astra should be adopted by the Court.

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